

From: [David G FARRER](#)
To: [Eric Blischke/R10/USEPA/US@EPA](#); [Poulsen, Mike](#)
Cc: danadavoli@avvanta.com; [Dana Davoli/R10/USEPA/US@EPA](#); [Chip Humphrey/R10/USEPA/US@EPA](#)
Subject: RE: Portland Harbor breast milk
Date: 04/08/2008 09:10 AM
Attachments: [BMletterHC.doc](#)
[BM letterHCApendix A.doc](#)

Eric,

The development of PRGs and clean-up numbers is outside the scope of DHS. I have submitted a modified version of the memo to ATSDR for endorsement as a letter addressed to the LWG (attached). The recommendation most important to DHS is the one asking LWG to fund a community outreach program geared toward identifying and educating the populations of women affected by subsistence fishing from the harbor. I hope that your decision does not obfuscate the usefulness of this letter (and especially that recommendation). I do think it is important that everyone understand that developing fetuses and nursing infants are the most sensitive to the adverse health effects of PCB exposure and that they get the highest dose. Does inclusion in the baseline risk assessment necessarily require that the RBC it generates be used in the development of PRGs?

David Farrer
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>>> <Blischke.Eric@epamail.epa.gov> 4/8/2008 7:30:16 AM >>>
Mike and others,

I sent the information around to the Puget Sound Fish Consumption group as Dana requested without much commentary on my part. However, after thinking about it further, I offer the following rebuttal to your question as to why we should not include this pathway.

- 1) The breast milk consumption exposure scenario is unlikely to drive cleanup levels. The cleanup levels for chemicals such as PCBs, dioxins and DDT will likely be determined based on background levels not risk-based levels. Driving the risk-based values lower will not advance our cleanup.
- 2) You note that we do not account for the benefits associated with eating fish as part of our risk assessment process. This is true. However, I believe that the benefits associated with breast feeding are far more significant in terms of a health immune system and other benefits than are the health benefits associated with eating fish.

For these reasons, I do not think we should evaluate this scenario in our baseline risk assessment. I believe that this pathway should be handled through Oregon's Department of Human Services which is in a far better position than Superfund to present information about the risks and benefits associated with breast feeding broadly and working to educate the public about the risks and benefits associated consuming fish collected from Portland Harbor.

I expect that fish consumption advisories and public outreach to make these advisories more effective and reliable will be a necessary part of our remedy. This will provide an opportunity to get information out to the public about the special risks faced by pregnant or nursing women who may consume fish collected from the Portland Harbor site.

Eric

"POULSEN Mike"
<POULSEN.Mike@de
q.state.or.us>
04/07/2008 11:22 AM
To
Eric Blischke/R10/USEPA/US@EPA
cc
Chip Humphrey/R10/USEPA/US@EPA,
Dana Davoli/R10/USEPA/US@EPA,
<danadavoli@avvanta.com>, "FARRER
David G"
<David.G.Farrer@state.or.us>
Subject
RE: Portland Harbor breast milk

Eric -

I've tried to address your questions below. I haven't proposed much revision to Dana's cover memo other than a statement along the lines of "give us a good reason why we shouldn't include this pathway, because we can't think of one."

- Mike

Cover memo does not really tee up the public policy issues.

I suggest we insert the following near the end of the first paragraph in Dana's cover memo: "We consider breast feeding to be an important exposure pathway, particularly for PCBs. Breast feeding has not been considered in most Superfund risk assessments, but we see no reason to exclude this pathway."

How are the benefits of breast feeding accounted for?

Benefits are not typically accounted for in risk assessments. For example, we do not present the benefits of eating fish. So we are not planning a risk-benefit analysis. However, benefits of breast feeding may be implicitly included if we use the ATSDR intermediate-duration MRL (instead of the chronic RfD). The MRL was developed during infant monkey exposure that would be consistent with the exposure period for a breast-feeding human infant.

What is the best way to present this information to the public in a non-alarmist way?

We acknowledge that the risk assessment will show potential risks associated with high fish consumption and associated bioaccumulation of

PCBs in the mother's body. The risk calculations are supported by public health studies that show health effects associated with PCB concentrations in breast milk. Our previous preliminary risk assessment conclusion that there are potential health effects to adults from consumption of PCBs in fish is now expanded to include potential health effects to offspring, which may in fact be more important. This conclusion is already included in the existing fish advisory for the site. We are now providing quantitative support for the statement in the advisory, so we are not really saying anything new. However, we recognize that this information may dissuade mothers from breast feeding. For this reason we provide in the memo proposed text to be included by the LWG in the risk assessment regarding the benefits of breast feeding and the public health recommendation to continue breast feeding. There will also be a separate document by DHS (with ATSDR review) that can be referred to.

Is this information necessary for making remedial action decisions at the site?

Yes. This is an important pathway, and appears to be the risk driver for PCBs.

And ultimately, what end result from assessing and presenting this scenario do we hope to achieve?

As with any important exposure pathway, we want to evaluate the associated risks and determine acceptable levels for cleanup. We cannot do this if we do not conduct a quantitative evaluation.

-----Original Message-----

From: Blischke.Eric@epamail.epa.gov

[mailto:Blischke.Eric@epamail.epa.gov]

Sent: Monday, April 07, 2008 10:09 AM

To: POULSEN Mike

Cc: Humphrey.Chip@epamail.epa.gov; Davoli.Dana@epamail.epa.gov;

danadavoli@avvanta.com; FARRER David G

Subject: RE: Portland Harbor breast milk

Based on a quick review of the memo, I have no issues with the methodology as it is written up. It seems to be a comprehensive summary of the methodology and very well presented. However, I have concerns about the cover memo because it does not really tee up the public policy issues - namely, how are the benefits of breast feeding accounted for? What is the best way to present this information to the public in a non-alarmist way? Is this information necessary for making remedial action decisions at the site? And ultimately, what end result from assessing and presenting this scenario do we hope to achieve?

I will try to touch base with Dana on this. In the meantime, I will make an attempt to insert some language that gets at the concerns I outlined above; any thoughts are welcome.

Thanks, Eric

"POULSEN Mike"
<POULSEN.Mike@de
q.state.or.us>

To

Eric Blischke/R10/USEPA/US@EPA,
04/07/2008 09:44 AM Chip Humphrey/R10/USEPA/US@EPA
cc
<danadavoli@avvanta.com>, Dana
Davoli/R10/USEPA/US@EPA, "FARRER
David G"
<David.G.Farrer@state.or.us>
Subject
RE: Portland Harbor breast milk

Chip & Eric -

I incorporated Dana's revisions in the main memo after making a few minor edits. I think this is in good shape to send out for EPA review. After your approval, of course. I didn't have any comments on the cover memo.

- Mike

-----Original Message-----

From: Davoli.Dana@epamail.epa.gov [<mailto:Davoli.Dana@epamail.epa.gov>]
Sent: Saturday, April 05, 2008 3:52 PM
To: POULSEN Mike; FARRER David G; Blischke.Eric@epamail.epa.gov; Humphrey.Chip@epamail.epa.gov
Cc: danadavoli@avvanta.com
Subject: Re: Portland Harbor breast milk

(b) (6)

I have attached slightly edited versions of both the memo to the EPA reviewers (marked up version and edits accepted version) and Mike's technical write-up (marked up only). For the memo to reviewers, I added Mike's comments and a few more statements/questions about the health consultation. For the technical document, I added some language from RAGs defining chronic exposure (Mike, could you please add the footnote correctly and add the the RAGs reference which is on the reference page to the list of references). I also made some edits so that the document is using 1 ppm for resident fish as an example (as opposed to bass). It seemed a bit easier to read and flows nicely into the statement that compares the 1ppm to bass and carp fish data in PH. I do not feel strongly about this so you guys can ignore the the changes if want to. I am hoping that Mike and Dave can look these over and get any final comments to Chip and Eric as early as possible on Monday.

Chip and Eric, I would like to have one of you send this to the Region 10 group (RPMs and risk assessors) that has been involved in the Puget Sound Tribal Seafood Consumption Framework. As I mentioned in yesterday's e-mail to you both, the group is meeting on Thursday afternoon (April 10) and I would like to have a brief discussion at the end of the meeting on this issue (hopefully with all of you on the

phone). It would be great if one of you could send the reviewers' memo and tech document/consult to the group by Tuesday. It doesn't have to be perfect as I am sure we will get comments on it. This is the mail group:

Allison Hiltner/R10/USEPA/US@EPA, Charles Ordine/R10/USEPA/US@EPA, Christy Brown/R10/USEPA/US@EPA, Dana Davoli/R10/USEPA/US@EPA, Erika Hoffman/R10/USEPA/US@EPA, Howard Orlean/R10/USEPA/US@EPA, Julius Nwosu/R10/USEPA/US@EPA, Lori Cohen/R10/USEPA/US@EPA, Marc Stifelman/R10/USEPA/US@EPA, Marcia Bailey/R10/USEPA/US@EPA, Michael Cox/R10/USEPA/US@EPA, Nancy Harney/R10/USEPA/US@EPA, Piper Peterson-Lee/R10/USEPA/US@EPA, Ravi Sanga/R10/USEPA/US@EPA, Rich McAllister/R10/USEPA/US@EPA, Rick Albright/R10/USEPA/US@EPA, Shawn Blocker/R10/USEPA/US@EPA, Sheila Eckman/R10/USEPA/US@EPA, Lon Kissinger/R10/USEPA/US

Lon is in charge of setting up the meetings and I have asked him to add this topic.

I will have my cell with me so you can call me at (b) (6) to discuss this.

Also below is some language from the SSL guidance that I found interesting:

EPA Soil Screening Guidance: Technical Background Document (<http://www.epa.gov/superfund/health/conmedia/soil/introtbd.htm>)

2.2 Direct Ingestion

Calculation of SSLs for direct ingestion of soil is based on the methodology presented for residential land use in RAGS HHEM, Part B (U.S. EPA, 1991b). Briefly, this methodology backcalculates a soil concentration level from a target risk (for carcinogens) or hazard quotient (for noncarcinogens). A number of studies have shown that inadvertent ingestion of soil is common among children 6 years old and younger (Calabrese et al., 1989; Davis et al., 1990; Van Wijnen et al., 1990). Therefore, the approach uses an age-adjusted soil ingestion factor that takes into account the difference in daily soil ingestion rates, body weights, and exposure duration for children from 1 to 6 years old and others from 7 to 31 years old. The higher intake rate of soil by children and their lower body weights lead to a lower, or more conservative, risk-based concentration compared to an adult-only assumption. RAGS HHEM, Part B uses this age-adjusted approach for both noncarcinogens and carcinogens. For noncarcinogens, the definition of an RfD has led to debates concerning the comparison of less-than-lifetime estimates of exposure to the RfD. Specifically, it is often asked whether the comparison of a 6-year exposure, estimated for children via soil ingestion, to the chronic RfD is unnecessarily conservative.

In their analysis of the issue, the SAB indicates that, for most chemicals, the approach of combining the higher 6-year exposure for children with chronic toxicity criteria is overly protective (U.S. EPA, 1993e). However, they noted that there are instances when the chronic RfD may be based on endpoints of toxicity that are specific to children (e.g., fluoride and nitrates) or when the dose-response curve is steep (i.e., the dosage difference between the no-observed-adverse-effects level [NOAEL] and an adverse effects level is small). Thus, for the purposes of screening, OERR opted to base the generic SSLs for noncarcinogenic contaminants on the more conservative

"childhood only" exposure (Equation 1). The issue of whether to maintain this more conservative approach throughout the baseline risk assessment and establishing remediation goals will depend on how the toxicology of the chemical relates to the issues raised by the SAB.

For noncarcinogens, averaging time is equal to exposure duration. Unlike RAGS HHEM, Part B, SSLs are calculated only for 6-year childhood exposure.

For carcinogens, both the magnitude and duration of exposure are important. Duration is critical because the toxicity criteria are based on "lifetime average daily dose." Therefore, the total dose received, whether it be over 5 years or 50 years, is averaged over a lifetime of 70 years. To be protective of exposures to carcinogens in the residential setting, RAGS HHEM, Part B (U.S. EPA, 1991b) and EPA focus on exposures to individuals who may live in the same residence for a "highend" period of time (e.g., 30 years). As mentioned above, exposure to soil is higher during childhood and decreases with age. Thus, Equation 2 uses the RAGS HHEM, Part B time-weighted average soil ingestion rate for children and adults; the derivation of this factor is shown in Equation 3.

(See attached file: 20080405 DAVOLI Final Draft of Letter to Reviewers.doc)(See attached file: 20080405 DAVOLI EDITS ACCEPTED Final Draft of Letter to Reviewers.doc)

(See attached file: 20080405 DAVOLI Final Draft Proposed Approach for Breastfeeding and Health Consultation .doc) (See attached file: 20080407 DAVOLI Final Draft Proposed Approach for Breastfeeding and Health Consultation.doc)